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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

RAJAN, KAI

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,493	Applicant(s) GOH ET AL.	
	Examiner Kai Rajan	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,7,9,30,32,34,35,37-42,47-55,57,58,60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,7,9,30,32,34,35,37-42,47-55,57,58,60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/22/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges the amendment filed November 4, 2009.

Response to Arguments

Applicant's arguments regarding newly added claim limitations have been considered but are moot in view of the new ground(s) of rejection (see rejection below).

Other arguments were not found persuasive. Applicant contends that Hatlestad fails to disclose "a physiological parameter correction factor that is individually determined for the person," and states that the claims "differentiate the physiological parameters of one individual among those of other individuals (November 4, 2009 response, pg 13). It is noted that the features upon which applicant relies (i.e., differentiation among other individuals) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Hatlestad discloses in paragraph 0027 correction factors and normalization determined based on the context of the particular patient, which comprises a correction factor "individually determined." As such, the applied reference is sufficient to reject the claim limitation as currently presented.

Note to Applicant Regarding Claim Interpretation

The term "adapted to" in the apparatus and system claims may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the

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intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Objections

Claims 1, 30, 47, and 61 are objected to because of the following informalities: The aforementioned claims disclose first and second thresholds, however the independent claims disclose the "second" threshold before the "first" threshold is discussed in dependent claim 61. The Examiner suggests amending the claim language so that it flows logically, addressing the threshold stated in the independent claim as the "first" threshold, and the subsequent threshold as the "second." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54, 55, 67, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaukel U.S. Patent No. 6,072,396.

54. A system for capturing and monitoring at least one physiological parameter and movement within an area of at least one person comprising:

a remote control unit (Gaukel figure 1 item 40 tracking station);

a plurality of access stations provided in a spatial arrangement within the area, thereby dividing the area into respective cells, wherein each access station has a respective station identifier and is connected to the control unit (Gaukel column 15 lines 16 – 39, column 18 lines 15 – 49, figures 10, 11); and

at least one physiological parameter measuring device that is attachable to a first person for measuring at least one physiological parameter of the first person to obtain a physiological parameter reading, each device having a device identifier and being connected to the respective access station of the cell when it is within the cell (Gaukel column 5 lines 62 – 64, column 8 lines 36 – 55);

wherein each access station is adapted to receive said physiological parameter reading and said respective device identifier from said at least one physiological parameter measuring device, and to transmit the received physiological parameter reading and the device identifier along with its station identifier to the control unit (Gaukel column 15 lines 16 – 39, column 18 lines 15 – 49, figures 10, 11 cellular system transmits data from user to cellular antenna stations, which is then sent to the tracking station.);

wherein the physiological parameter reading, device identifier, station identifier and a time at which the physiological parameter reading is obtained by the device are stored in a first record at the control unit (Gaukel column 6 lines 30 – 47, column 12 lines 12 – 32);

wherein the at least one physiological parameter measuring device comprises:

a transducer (Gaukel figure 1 item 24 thermistor is a transducer);
a transmitter (Gaukel figure 1 item 34 at least cellular phone and modem are transmitters); and
a processor connected to the transducer and the transmitter (Gaukel figure 1 items 36 and 28 CPUs),
said physiological parameter measuring device further comprising a housing including:
a first portion (Gaukel figure 1 item 30 “cellular bag”);
a second portion (Gaukel figure 1 item 20 wrist band); and
a flexible medial portion connected between the first and the second portion, wherein the processor, transmitter and receiver are accommodated within the first housing portion and the transducer is supported on the second housing portion (Gaukel figure 1 item 68 cable connects the cellular bag which contains a processor, transmitter, and receiver to the wrist worn device which contains a transistor).

55. The system of according to Claim 54, wherein the processor is adapted to control the transducer to at least intermittently measure the physiological parameter of the first person and to control the transmitter to transmit the physiological parameter reading (Gaukel column 8 lines 15 – 22, column 19 lines 56 – 67, column 20 lines 1 – 13).

Claims 57 and 58 are rejected on substantially the same basis as the rejection presented in the previous action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7, 9, 30, 32, 34, 35, 37 – 42, 47 – 53, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaukel U.S. Patent No. 6,072,396 in view of Hatlestad U.S. PGPub No. 2004/0073093, further in view of Groff et al. U.S. Patent No. 6,102,856 (“Groff”).

Note to Applicant: see previous action for rejection of unaddressed dependent claims, as they are rejected on substantially the same basis.

1. A method of capturing and monitoring at least one physiological parameter and movement within an area of at least one person, the method comprising:

dividing the area into cells having respective location identifiers by providing a plurality of access stations in spatial arrangement within the area, thereby dividing the area into the cells (Gaukel column 15 lines 16 – 39, column 18 lines 15 – 49, figures 10, 11);

providing each person with a respective device for measuring at least one physiological parameter of each person, the physiological parameter being indicative of whether the person has

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a physical condition, each device having a device identifier (Gaukel column 5 lines 62 – 64, column 8 lines 36 – 55);

at least intermittently measuring a physiological parameter of each person using the respective device to obtain a physiological parameter reading for each measurement (Gaukel column 8 lines 15 – 22, column 19 lines 56 – 67, column 20 lines 1 – 13);

associating each of at least a selected number of the physiological parameter readings with the respective device identifier of the device by which, the respective location identifier of the cell in which, and a time at which the physiological parameter reading is obtained (Gaukel column 12 lines 12 – 32);

storing the associated physiological parameter reading, device identifier, location identifier and time (Gaukel column 6 lines 30 – 47);

comparing the physiological parameter reading with a second physiological parameter threshold value to determine if the person has a physiological condition wherein the physiological parameter is body temperature (Gaukel column 12 lines 45 – 67, column 13 lines 1 – 25, column 19 lines 56 – 67, column 20 lines 1 – 13. Gaukel discloses monitoring the body temperature of a wearer, as well as blood pressure and heart rate which are compared to tolerances for detecting alert conditions. Furthermore, Gaukel teaches monitoring patient signs for alert medical conditions, yet fails to include temperature as a monitored condition other than collecting temperature data in column 1 lines 20 – 45. As such, Gaukel fails to state the body temperature is compared to tolerances to detect alert conditions. However, it would have been obvious to one of ordinary skill in the art to modify the invention of Gaukel to use body

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temperature data compared to tolerances to detect alert conditions, since it is known in the art of physiological monitoring to monitor vital signs for conditions, and temperature is a vital sign.);

Gaukel discloses monitoring physiological signals and detecting alarm conditions (Gaukel column 8 lines 15 – 22, column 19 lines 56 – 67). Gaukel is silent regarding applying correction factors to the measured signals. However, Hatlestad, a reference in an analogous art, discloses a physiological monitoring and transmitting system that applies correction factors to the measured waveforms to compensate for the context in which the data is measured (Hatlestad paragraph 0027). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the system of Gaukel with the correction factors of Hatlestad, since Hatlestad states that applying correction factors to compensate for the context in which physiological data is measured increases the reliability of the measured data and improves assessments of the patient's health (Hatlestad paragraphs 0003 – 0005).

Furthermore, Gaukel and Hatlestad disclose comparing physiological data to tolerances determined for each person for detecting alert conditions (Gaukel column 19 lines 56 – 67, column 20 lines 1 – 13). Gaukel and Hatlestad fail to disclose determining those tolerances based on mean values with added standard deviations. However, Groff a reference in an analogous art of physiological data monitoring including temperature data teaches setting data thresholds at one or more standard deviations from the normal data pattern (Groff column 3 lines 41 – 53). “Normal data pattern[s]” are known to those in the physiological data art as average or mean readings over time. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the individually determined tolerances of Gaukel and Hatlestad with the standard deviation calculations of Groff, since Groff teaches standard deviations as

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useful for recognizing anomalous data indicative of alert conditions in otherwise normal data patterns (Groff column 3 lines 41 – 53).

Claims 2, 4, 6, 7, and 9 are rejected on substantially the same basis as the rejection presented in the previous action.

Claim 30 is rejected on substantially the same basis as claim 1, see above.

Claims 32, 34, 35, and 37 – 42 are rejected on substantially the same basis as the rejection presented in the previous action.

Claim 47 is rejected on substantially the same basis as claim 1, see above.

Claims 48 – 53 and 60 are rejected on substantially the same basis as the rejection presented in the previous action.

61. The method according to claim 1, comprising comparing the physiological parameter reading with a first predetermined physiological parameter threshold value to determine if the person is wearing the device properly (Gaukel column 12 lines 66 – 67, column 13 lines 1 – 11).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
3769

March 24, 2010